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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/020,389	10/30/2001	Paul Higham	OSTEONICS 3.0-352	2177

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EXAMINER

FONTAINE, MONICA A

ART UNIT PAPER NUMBER

1732

DATE MAILED: 04/14/2003

4

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/020,389

Applicant(s)

HIGHAM ET AL.

Examiner

Monica A Fontaine

Art Unit

1732

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 6) ☐ Other:

Art Unit: 1732

DETAILED ACTION

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:
It does not identify the citizenship of each inventor.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Refojo (U.S. Patent 4,452,776).

Regarding Claim 1, Refojo shows that it is known to carry out a method for forming a hydrogel medical implant (Column 2, lines 53-55) comprising preparing a hydrogel solution (Column 3, lines 46-49), injecting the solution into a mold (Column 3, lines 46-50), causing said molded solution to gel (Column 3, lines 65-66), washing said molded gel in a physiological solution (Column 3, lines 65-68 – Column 4, lines 1-2), dehydrating the molded gel (Column 5, lines 18-20), and packaging the implant (Column 5, lines 20-22).

Art Unit: 1732

Regarding Claims 2 and 3, Refojo shows the process as claimed as discussed above, including a method wherein said washing takes place for several weeks (Column 5, lines 9-12).

Regarding Claim 8, Refojo shows the process as claimed as discussed above, including a method wherein the dehydration reduces the water content of the gel to its approximate in vivo equilibrium water content (Column 4, lines 11-16).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Refojo.

Regarding Claim 4, Refojo shows the process as claimed as discussed above, including a method wherein the physiologic solution is 0.9% sodium chloride solution (Column 7, lines 15-17).

Although it is not specifically stated in Refojo, it would have been obvious to one of ordinary skill in the art at the time the invention was made to buffer the sodium chloride solution with phosphates in order to increase the compatibility of the implant with normal fluids present in humans. Regarding Claim 11, Refojo shows the process as claimed as discussed above, including a method wherein said washing in said saline solution is until no measurable amount of impurities remain in the implant (Column 4, lines 3-6). Although no time period is explicitly specified, it would have been obvious to one of ordinary skill in the art at the time the invention was made to be aware that the washing process could possibly take at least one day.

Claims 5-7, 9-10, 12-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Refojo, in view of Molock et al. (U.S. Patent 5,681,871).

Regarding Claim 5, Refojo shows the basic process as claimed as discussed above, but does not show carbonate in his saline solution. Molock et al., hereafter "Molock," show that it is known to carry out a process wherein the saline solution further contains a potassium carbonate solution (Column 7, lines 54-60). Molock and Refojo are combinable because they are concerned with a similar technical field, namely, that of forming hydrogel implants. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include Molock's potassium carbonate in Refojo's saline solution in order to make it more compatible with human fluid.

Regarding Claims 6 and 7, Refojo shows the basic process as claimed as discussed above, but does not specify concentrations of the saline solution. Molock shows that it is known to carry out a process wherein the potassium carbonate solution is 2 weight percent (0.14M) (Column 7, lines 54-60). Although Molock's molarity is outside of the claimed range, the difference between the Molock's molarity and the highest value of the claimed range is approximately 36%, and it is not clear what advantages would be present when using the claimed concentration instead of Molock's concentration. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use Molock's concentration during Refojo's molding process in order to provoke a desired product which results from a 0.05M potassium carbonate wash.

Regarding Claim 9, Refojo shows the basic process as claimed as discussed above, but does not include any provisions related to radiation. Molock shows that it is known to carry out

Art Unit: 1732

a process which includes irradiating the molded gel after said washing (Figure 1). It would have been obvious to one of ordinary skill in the art at the time the invention was made to irradiate the molded gel after washing in order to test its durability in environments having radiation.

Regarding Claim 10, Refojo shows the basic process as claimed as discussed above, but does include any provisions related to radiation. Molock shows that it is known to carry out a process wherein the molded gel is hydrated to about 80% water content prior to irradiation (Column 6, lines 5-9). It would have been obvious to one of ordinary skill in the art at the time the invention was made to hydrate molded gel prior to irradiation, as in Molock, during Refojo's molding process in order to insure proper water content to prevent disintegration of the gel during irradiation.

Regarding Claim 13, Refojo shows a process for treating a hydrogel (Column 3, lines 46-50) comprising forming a hydrogel and washing the hydrogel in a saline solution (Column 3, lines 46-68 – Column 4, lines 1-2). Refojo does not show a saline solution including potassium carbonate. Molock shows that it is known to carry out a process wherein a hydrogel is washed with a potassium carbonate solution (Column 7, lines 54-60). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include Molock's potassium carbonate in Refojo's saline solution in order to make it more compatible with human fluid.

Regarding Claim 14, Refojo shows the basic process as claimed as discussed above, but does not specify concentrations of the saline solution. Molock shows that it is known to carry out a process wherein the potassium carbonate solution is 2 weight percent (0.14M) (Column 7, lines 54-60). Although Molock's molarity is outside of the claimed range, the difference between the Molock's molarity and the highest value of the claimed range is approximately 36%,

Art Unit: 1732

and it is not clear what advantages would be present when using the claimed concentration instead of Molock's concentration. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use Molock's concentration during Refojo's molding process in order to provoke a desired product which results from a 0.05M potassium carbonate wash.

Regarding Claims 15 and 16, Refojo shows the basic process as claimed as discussed above, including washing the hydrogel for at least one day (Column 5, lines 9-12), meeting applicant's claim.

Regarding Claim 17, Refojo shows the basic process as claimed as discussed above, but does not show heating the washing solution. Molock shows that it is known to carry out a method wherein the washing solution is heated (Column 7, lines 54-57). It would have been obvious to one of ordinary skill in the art at the time the invention was made to heat the washing solution, as in Molock, during Refojo's molding process in order to make the solution more effective in cleansing the molded hydrogel.

Regarding Claim 18, Refojo shows the basic process as claimed as discussed above, but does not show heating the washing solution to a specific temperature. Molock shows that it is known to carry out a method wherein the washing solution is heated to 35°C (Column 7, lines 57-60). Although this temperature is not exactly the claimed temperature, it is not clear from the specification the advantage that would be present at a temperature 2 degrees Celcius higher than Molock's. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to heat the washing solution to Molock's temperature during Refojo's molding process in order to make the solution more effective in cleansing the molded hydrogel.

Regarding Claim 19, Refojo shows the basic process as claimed as discussed above, but does not show a phosphate buffered saline solution having potassium carbonated added thereto. Refojo shows a method wherein the physiologic solution is 0.9% sodium chloride solution (Column 7, lines 15-17). Although it is not specifically stated in Refojo, it would have been obvious to one of ordinary skill in the art at the time the invention was made to buffer the sodium chloride solution with phosphates in order to increase the compatibility of the implant with normal fluids present in humans. Furthermore, Molock shows that it is known to carry out a process wherein the potassium carbonate solution is 2 weight percent (0.14M) (Column 7, lines 54-60). Although Molock's molarity is outside of the claimed range, the difference between the Molock's molarity and the highest value of the claimed range is approximately 36%, and it is not clear what advantages would be present when using the claimed concentration instead of Molock's concentration. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use Molock's concentration during Refojo's molding process in order to provoke a desired product which results from an approximately 0.05M potassium carbonate wash.

Regarding Claim 20, Refojo shows the basic process as claimed as discussed above, but does not specify concentrations of the saline solution. Molock shows that it is known to carry out a process wherein the potassium carbonate solution is 2 weight percent (0.14M) (Column 7, lines 54-60). Although Molock's molarity is outside of the claimed range, the difference between the Molock's molarity and the highest value of the claimed range is approximately 36%, and it is not clear what advantages would be present when using the claimed concentration instead of Molock's concentration. Therefore, it would have been obvious to one of ordinary

Art Unit: 1732

skill in the art at the time the invention was made to use Molock's concentration during Refojo's molding process in order to provoke a desired product which results from a 0.05M potassium carbonate wash.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Refojo, in view of Suminoe et al. (U.S. Patent 4,550,001). Refojo shows the basic process as claimed as discussed above, but does not show specific elements added to the saline solution. Suminoe et al., hereafter "Suminoe," show that it is known to carry out a method wherein a sodium chloride solution includes potassium phosphate (Column 4, lines 39-41, 49, 60-62). Suminoe and Refojo are combinable because they are concerned with a similar technical field, namely, that of molding hydrophilic articles. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use Suminoe's potassium phosphate in Refojo's molding process in order to utilize a different or additional solution or to provoke a specific product whose properties result from the use of potassium phosphate.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following patents are cited to further show the state of the art with regard to molding hydrogel in general:

U.S. Patent 3,957,362 to Mancini et al.

U.S. Patent 3,992,563 to Tanaka

U.S. Patent 5,733,563 to Fortier

U.S. Patent 6,368,522 to Ansell et al.


Art Unit: 1732

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Monica A Fontaine whose telephone number is 703-305-7239. The examiner can normally be reached on Monday-Friday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill L. Heitbrink can be reached on 703-308-0673. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9310 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

maf
April 10, 2003


JILL L. HEITBRINK
PRIMARY EXAMINER
ART UNIT 1732
4/11/03